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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,594	08/25/2000	Malcolm King	11157-14	4598

1059 7590 12/18/2002

BERESKIN AND PARR
SCOTIA PLAZA
40 KING STREET WEST-SUITE 4000 BOX 401
TORONTO, ON M5H 3Y2
CANADA

EXAMINER	
WELLS, LAUREN Q	
ART UNIT	PAPER NUMBER
1617	18

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/645,594	KING, MALCOLM	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,27 and 28* is/are pending in the application.

4a) Of the above claim(s) *27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-19 and 27-28 are pending. Claims 27-28 are withdrawn from consideration, as they are directed toward non-elected subject matter.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/23/02 has been entered.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a method of administering a composition, classified in class 514, subclass 59.

II. Claims 1 and 27, drawn to a method of diagnosing, classified in class 436, subclass 2.

III. Claims 1 and 28, drawn to a method of determining a dosage regime, classified in class 427, subclass 2.11.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are distinct. Group I functions to treat a disease and is an in vivo method, whereas

Group II functions to diagnosis a disease and is an in vitro method, and Group III functions to determine how much medication to administer to a patient and is an in vitro method.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are distinct. Group II functions to diagnosis a disease and Group III functions to determine how much medication to administer to a patient.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Anita Nador on 10/18/02 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27-28 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The combination of claim 1 and 7 is vague and indefinite, as a) claim 7 depends on claim 1, yet claim 7 is broader than claim 1, and b) claim 7 comprises administering to an animal and claim 1 comprises administering to mucus. As a result, these claims are confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Beller et al. (Case Reports).

Beller et al. teach that a 10% solution of dextran sulfate was sufficient for lysis of mucus and that 500ml of a 10% solution of dextran sulfate allowed the removal of 1800ml of mucus. Also disclosed is intra-abdominal instillation of 100ml of a 5% solution of dextran sulfate, wherein 1400ml of mucus was removed. Thus, Beller et al. and the instant invention both teach a method of administering to the mucus in a human, an effective amount of dextran sulfate. See pg. 970-971.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-5, 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speert et al. (5,514,665).

The instant invention is directed to a method of administering to the mucus, an effective amount of charged dextran.

Speert et al. teach a method of administering a composition comprising dextran or dextran sulfate to cystic fibrosis patients. An aerosol, wherein administration is via inhalation, is a disclosed form of the composition. A dosage of 10-20mmol of dextran sulfate is disclosed, wherein 20mmol is 160mg/ml of dextran sulfate in solution. The reference lacks the explicit step to administering dextran sulfate to mucus. See Col. 4, line 30-line 55; Col. 5, line 11-Col. 7, line 26; Col. 9, line 63-Col. 12, line 11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the method of Speert et al. wherein the composition comprising dextran sulfate is administered to mucus because a) Speert et al. teach their compositions as being administered to Cystic Fibrosis patients, and Webster's Dictionary defines Cystic Fibrosis as 'a common hereditary disease especially among whites that appears usually in early childhood, involves functional disorder of the exocrine glands, and is marked especially by faulty digestion due to a deficiency of pancreatic enzymes, by difficulty in breathing due to ***mucus accumulation in airways***, and by excessive loss of salt in the sweat'; b) administration of an aerosol composition, via inhalation, is directly administered to the respiratory tract; thus, one of skill in the art would have taught the method of Speert et al. as administering a dextran sulfate composition to the mucus because Cystic Fibrosis patients have mucus in their airways and aerosol inhalation administers active agents to the respiratory tract.

Claims 3, 6, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speert et al. as applied to claims 1-2, 4-5, 7-17 above, and further in view of Kennedy (WO 91/15216).

Speert et al. is applied as discussed above. The reference lacks preferred molecular weights of dextran sulfate.

Kennedy teaches a method of applying a polysulphated polysaccharide to a host via aerosolization, wherein dextran sulfate is disclosed as a polysulfated polysaccharide. Dextran sulfate is disclosed as having a molecular weight of less than 10,000 and as preferably 5000 or 8000. See pg. 8, line 22-pg. 9, line 25; pg. 18-19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the dextran sulfate of Speert et al. as having a molecular weight of 5000, as taught by Kennedy, because a) Speert and Kennedy teach the same method of administering the same composition; and b) it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980); thus, one of skill in the art would be motivated to teach the dextran sulfate of Speert et al. as having a molecular weight of 5000.

Response to Declaration

Applicant's 1.132 Declaration filed 9/23/02, Paper No. 17, with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection. However, to the extent that the declaration may be relevant to the instant rejection, the Examiner will address them.

Declaration states, "The patent (in reference to Speert et al.) does not teach anything about effects of dextrans on mucus clearance". This argument is not persuasive. The Examiner

respectfully points out that the Speert et al. reference teaches the same method of administering the same composition. Therefore, Speert et al. inherently has the effects on mucus clearance.

Declaration sates "Dr. King's '594 patent application teaches that dextran sulfate can correct his problem and proposes a mechanism of action altogether distinct from that in my patent and results in a different medical application for dextran sulfate". This argument is not persuasive. The Examiner respectfully points out that declarations must set forth facts, not merely conclusions. In re Pike, 1950 C.D. 105, 84 USPQ 235. In the instant case, there are no factual showings that the mechanism is different. Further, the Examiner respectfully points out that the medical application is not different, as the instant reference and Speert et al. both teach inhalation administration of dextran sulfate.

Declaration states, "Beller et al. . .This mucus is quite different from that of the respiratory tract. . .The patients in Beller received either 10% or 5% dextran sulfate by the molecular weight was not described. Beller's use and the nature of the mucus lysed by the dextran sulfate are quite distinct from that described in Dr. King's '594 patent application". This argument is not persuasive, as it is not commensurate in scope with the independent claim, which is not limited to repiratory tract mucus, dextran sulfate, or a molecular weight.

Declaration states, "Kennedy teaches that dextran sulfate has anti-elastase activity. . .There is not mention in Kennedy of respiratory tract mucus. This use is altogether different from that taught by the '594 patent application". This argument is not persuasive. the Examiner respectfully points out that Kennedy was merely relied upon to teach molecular weights of dextran sulfate.

Response to Arguments

Applicant's Arguments filed 9/23/02, Paper No. 16, with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection. However, to the extent that the arguments may be relevant to the instant rejection, the Examiner will address them.

Applicant argues, "From. . .Dr. Speert's declaration, it is clear that none of the references noted by the Examiner teach a method of altering the rheology of respiratory tract mucus". This argument is not persuasive. Again, the Examiner respectfully points out that the Speert et al. teach the same method of administering the same composition. Therefore, Speert et al. inherently have the property of altering the rheology of respiratory tract mucus.

Applicant argues, "Beller et al. disclose the use of dextran sulfate to lyse a substance that is chemically very different from respiratory tract mucus". This argument is not persuasive, as it is not commensurate in scope with independent claim 1, which is not limited to respiratory tract mucus.

Notes/Suggestions

(i) Claim 10, line 2, "bronchitis" is spelled incorrectly.

(ii) Claim 15, line 2, the term "form" is spelled incorrectly.

The Examiner respectfully requests that Applicant correct these mistakes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
October 18, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER

11/27/02

SREENI PADMANABHAN
PRIMARY EXAMINER